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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/620,396 | 07/16/2003 | Benjamin Mark Skead | CELL-0272 | 2924 |
| 23377 | 7590 | 09/15/2004 | EXAMINER | |
| WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103 | | | AULAKH, CHARANJIT | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,396

Applicant(s)

SKEAD ET AL.

Examiner

Charanjit S. Aulakh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27 is/are rejected.
- 7) ☒ Claim(s) 26 and 28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. According to a preliminary amendment filed on Aug. 14, 2003, the applicants have amended claims 1, 3, 6, 9, 11, 14-16 and 19-25.
2. Claims 1-28 are pending in the application.

Specification

3. The disclosure is objected to because of the following informalities: On page 1, line 10, the number of international patent application is wrong. It should be WO 02/068,393. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claims 1, 25 and 27, the value of variable R1 defined as ----derivative or biostere----is indefinite since specific values are not defined and furthermore, the meaning of these terms is not clear.

In independent claims 1, 25 and 27, the values of variables Rx, Ry and Rz defined as ---an atom ----are indefinite since it is not clear which atom is being referred here.

In independent claims 1, 25 and 27, the value of variable L1 defined as ---linker atom or group --- is indefinite since it is not clear which atom or group is being referred here.

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In independent claims 1, 25 and 27, the value of variable ALK1 defined as ----heteroaliphatic chain---- is indefinite since the type, number and exact location within the aliphatic chain of heteroatoms is not defined.

In claims 15, 17 and 18, the value of ALK7 for variable R1 is not defined.

In claim 16, it is not clear what is the difference between two different compounds of formulae (1).

In claims 19 and 20, the value of variables R16, R17 and R18 defined as ---an atom--- are indefinite since it is not clear which atom is being referred here? Also, the values of L3, Alk2, L4, R5 and u are not defined.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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8. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey (WO 02/068,393, cited on applicants form 1449).

Bailey discloses Phenylalanine enamide derivatives possessing a cyclobutane group, for use as integrin inhibitors which do anticipate the instant compounds of formula (1). Bailey also teaches a process for preparing these compounds (see page 50, line 20 to page 63, line 23). The process of Bailey differs from the instant process that it does not recite all the steps in a sequence and furthermore, does not specifically mentions intermediate compounds of formulae (2), (4) and (5). However, Bailey does teach all the steps and intermediates generically (see specifically page 55, lines 12-28, page 50, line 20 to page 51, line 11, page 61, lines 22-29 and page 63, lines 18-23). Bailey further teaches preparing preferred compounds of formulae 2(a) to 2(d) on pages 28- 30 which anticipate the specific compounds of instant claims 19-24. Therefore, it would have been obvious to one skilled in the art to arrive at the instant process from the generic teachings of Bailey since Bailey does teach all the steps for preparing various intermediates and the final product.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Bailey (WO 02/068,393, cited on applicants form 1449).

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Bailey discloses Phenylalanine enamide derivatives possessing a cyclobutane group, for use as integrin inhibitors. The compounds disclosed in examples 64-68, 70, 105, 143, 171, 172 and 190-195 by Bailey anticipate the instant claim when R4 represents optionally substituted alkyl group in the instant compounds of formula (2).

Allowable Subject Matter

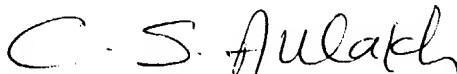
10. Claims 26 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
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